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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,812	12/04/2001	Mostafa Ronaghi	A34454-PCT-USA	8861

7590 02/27/2004

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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,812	<b>Applicant(s)</b> RONAGHI, MOSTAFA	
	<b>Examiner</b> Kenneth R Horlick	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,7,8,10 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8 and 10 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. It is noted that examination of this application is now being handled by a different examiner.
2. Upon consideration of the response filed 01/26/04, all previous rejections made in the final Office action mailed 08/26/03 are hereby withdrawn.
3. In light of the following new grounds of rejection, the finality established in the Office action mailed 08/26/03 is hereby withdrawn.

**NEW GROUNDS OF OBJECTION/REJECTION**

4. The specification is objected to because of the following informalities:
  - A) the misspelling "pyrophospate" in the last line of claim 1;
  - B) the misspelling "luiferase" in claim 15;
  - C) the specification lacks the mandatory heading "Brief Description of the Drawings".

Correction is required.

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5. Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are confusing because of the language "characterized in that" in claim 1, as the scope is unclear. It is suggested that this be replaced by conventional U.S. claim language such as "comprising" or "wherein", for which the meaning is clear.

B) These claims are further confusing because of a lack of active method step(s). While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). In other words, it is suggested that claim 1 be amended to include steps such as "providing a sample nucleic acid", "hybridizing a primer", "carrying out a polymerase reaction", etc.

C) Claims 2 and 3 are confusing because of the improper Markush language "selected from the group comprising" in claim 2. One acceptable form of Markush language is "selected from the group consisting of".

D) Claim 7 is confusing because it depends from cancelled claim 6.  
Correction is required.

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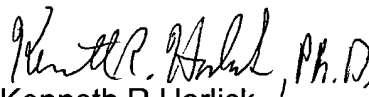
6. Pending claims 1-5, 7, 8, 10, and 15 are free of the prior art, but are objected to or rejected for other reasons. Claims 1-5, 7, 8, and 10 require carrying out a polymerase reaction in which a primer is used to detect the identity of a nucleotide base of interest, wherein a single-stranded nucleic acid binding protein is included in the reaction and is added after hybridization of the primer to the sample nucleic acid, and incorporation of nucleotide is detected by monitoring release of inorganic pyrophosphate. Ronaghi et al. (1998) teach primer extension methods based on detection of pyrophosphate release, but single-stranded nucleic acid binding protein is not used. While Studier et al. disclose a method in which single-stranded nucleic acid binding protein is used with primers, said protein is added during primer hybridization, not after primer hybridization. Rapley teaches the use of single-stranded nucleic acid binding proteins in PCR amplification and sequencing methods, but said methods do not involve pyrophosphate detection. With respect to kit claim 15, no prior art has been found teaching or suggesting the combination of reagents as required, which combination is useful in carrying out the claimed methods.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick, Ph.D.  
Primary Examiner  
Art Unit 1637

02/24/04